



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|-----------------------|------------------|
| 10/824,964 | 04/15/2004 | G. Ian Rowlandson | 140822IT (5024-00138) | 7468 |

7590 06/18/2007
Joseph D. Kuborn
Andrus, Sceales, Starke & Sawall, LLP
Suite 1100
100 East Wisconsin Avenue
Milwaukee, WI 53202-4178

| |
|----------|
| EXAMINER |
|----------|

MORALES, JON ERIC C

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

3766

| | |
|-----------|---------------|
| MAIL DATE | DELIVERY MODE |
|-----------|---------------|

06/18/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/824,964

Applicant(s)

ROWLANDSON ET AL.

Examiner

Jon-Eric C. Morales

Art Unit

3766

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 22 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 3/16/2007.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. In light of applicant's amendment, the objection of claim 1 is withdrawn.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-2, 6, 9-11, 15-16, and 19-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Valikai et al. (US Patent No. 5948005). Regarding claims 1, 6, 15-16 and 19-20, Valikai shows a system that includes an implantable pacemaker, which records heart rate/event data. There is also an external programmer that generates (transmits) a request signal (polling signal) for the implantable device to communicate with and also has a receiving unit (receiver) that acquires data from the implantable device as well as sensed data from a physiological sensor (column 6 lines 17-32). The physiological sensor is disclosed as being coupled either within the pacemaker or just coupled outside the pacemaker (column 5 lines 32-39). The physiological sensor either way senses data such as physical activity, respiration rate, or blood oxygen level (non-implant cardiac data) (column 1 lines 58-64, column 7 lines 9-28). The external programmer is controlled by a programming code (software program) loaded in the microprocessor of the programmer (column 8 lines 8-15). The programming code

Art Unit: 3766

allows the programmer to stores heart rate data from the implanted cardiac device (electronic implant cardiac data) as well as physiological data acquired from the physiological sensor coupled to the implanted pacemaker (column 9 lines 38-57). The data (physiological data and implanted cardiac data) is then correlated to produce a histogram chart (signature pattern) (column 11 lines 22-67, column 12 lines 15-33, Fig. 7-8). All the data, heart rate, event, or the histogram graph can be displayed on the external programmer display (column 22 lines 50-67, column 23 10-11, column 24 lines 1-9).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 3 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Valikai et al. (US Patent No. 5948005) as applied to claim 1 and 10 above, and further in view of Peel, III (US 6647287). Valikai discloses the invention substantially as claimed however does not show assigning at least one if a date and time to at least one of the non-implant cardiac data and the implant cardiac data. Peel discloses a time reference is measured for a start of each blood pressure pulse in the ECG measurement (column 34 lines 17-19). This is to synchronize any of the data of the cardiac patient. Therefore it would have been obvious to one of ordinary skill in the art, at the time of the invention, to modify the device of Valikai by adding a time reference to cardiac data as taught by Peel, III in order to facilitate synchronization of any cardiac data of a patient.

7. Claims 4 and 13 rejected under 35 U.S.C. 103(a) as being unpatentable over Valikai et al. (US Patent No. 5948005) as applied to claims 1 and 10, and further in view of Stomberg et al. (US 2005/0103351 Valikai substantially discloses the invention as claimed, however does not show a synchronization with time of data from a non-implantable medical device and data from an implantable medical device. Stomberg discloses a method using an external medical device as a reference time when taking measurements of time with the implantable medical device (page 6 sections [0061-0063]). This is to allow for correction of a time drift that occurs in an implantable medical device. Therefore it would have been obvious to one of ordinary skill in the art, at the

time of the invention, to modify the method of Peel, III by adding the time synchronization method, that uses a at least one time reference of a external medical device and a time reference of the clock in an implantable medical device, as taught by Stomberg in order to facilitate a correction of any type of time drift that can occur from a implantable medical device.

8. Claims 5 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Valikai et al. (US Patent No. 5948005) as applied to claims 1 and 10, in view of Shimoni (US Patent No. 4616333). Valikai substantially discloses the invention as claimed, however does not show alignment of non-implant and implant cardiac data to at least one fiducial point. Shimoni discloses a method that obtains a first set of values dealing with data (any form of data) with a certain number of points, then obtaining a second set of data (any type of data) with the same number of points as the first set, the selecting a subset of data points. Then selecting a fiducial value within the first data set and another fiducial point in the subset. Theses values are used as points for alignment with use of a calculation with the first set and the subset data points (column 2 lines 63-68 column 3 lines 6-13). Therefore it would have been obvious to one of ordinary skill in the art, at the time of the invention, to modify the method of Peel, III by adding the calculation process of two data sets with use of a fiducial point as a marker as taught by Shimoni in order to facilitate an alignment and correlation of two data sets.

9. Claims 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Valikai et al. (US Patent No. 5948005) as applied to claim 1 and further in view of Peel, III (US 6647287). Valikai discloses the invention substantially as claimed however does

Art Unit: 3766

not show comparing a signature pattern to determine the effectiveness of a current treatment and a display monitor. Peel, III discloses a display monitor to show representations of any of the patient data. The data provided can include any of the implantable blood pressure sensors or ECG data (column 29 lines 36-39). The disclosed display monitor is to visually assist in the diagnosis of the condition and effects of the treatments for a patient. Peel, III discloses a selection of choices, including ECG data, plethysmograph, and any one of the pulse oximeter measurements for use in the mathematical models (column 34 lines 33-37). Therefore it would have been obvious to one of ordinary skill in the art, at the time of the invention, to modify the device of Valikai by adding a display monitor as taught by Peel, III in order to facilitate visualization and diagnosis of patients cardiac data and the effectiveness of the treatment provided.

10. Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Valikai et al. (US Patent No. 5948005) as applied to claim 15, and further in view of Bardy (US 2002/0099302). Valikai substantially discloses the invention as claimed, however Valikai does not show the monitoring system of the patient is adapted to communicate with other devices on a network and the data can be received for the monitor from the networks other devices. Bardy discloses a system that sends data from the implantable medical device to an external medical device. The external device then sends the data to a server via an inter-network. This data is placed into a patient care file on a database (page 3 section 0032). The patient care file, on the database, can be accessed by medical devices located on the network for later use Therefore it

would have been obvious to one of ordinary skill in the art, at the time of the invention, to modify the system and implantable medical device (i.e. pacemaker) of Valikai by adding the inter-network server communication to a database, as taught by Bardy in order to exchange patient data and store data on a centralized database for later use.

Response to Arguments

11. Applicant's arguments with respect to claims 1-3, 6-12 and 20 have been considered but are moot in view of the new ground(s) of rejection.

12. Applicant's arguments filed 5/22/2007 have been fully considered but they are not persuasive. Regarding claims 15-16 and 19 examiner finds that Valikai does teach means collecting non-implant data. A physiological sensor is disclosed as being coupled either within the pacemaker or just coupled externally from the pacemaker (column 5 lines 32-39). The physiological sensor either way senses data such as physical activity, respiration rate, or blood oxygen level (non-implant cardiac data) (column 1 lines 58-64, column 7 lines 9-28). Coupling is just an interaction between the implanted device and physiological sensor. The physiological sensor can be implanted with the pacemaker it also doesn't have to be. The physiological sensor of Valikai can sense blood oxygen levels. Thus this sensor, coupled to the pacemaker, could be an external pulse oximeter (non-implanted device) that uses a finger probe to measure the blood oxygen levels of a patient.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

The following patent and patent application publications are cited and further show the state of the art with respect to implant cardiac data and non-implant cardiac data correlation and synchronization in general:

Manolas - US 2003/0204145

Crosby et al. - US 7074194

Hirsh US - 7054679

Sahai - US 6654631

Raymond et al. - US 6640134

Ripart - US 6385485

Art Unit: 3766

Sohma et al. - US 6129677

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon-Eric C. Morales whose telephone number is 571-272-3107. The examiner can normally be reached on Monday through Friday from 8am - 5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jon-Eric Morales
Patent Examiner
Art Unit 3766

Carl H. Layno
Carl Layno
Acting Supervisory Patent
Examiner
Art Unit 3766

JEM

CARL LAYNO
PRIMARY EXAMINER